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Acceptability of a Wearable Vital Sign Detection System

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This study assessed the human factors issues associated with wearing a Vital Sign Detection System (VSIDS), a body worn physiological monitoring system. Experienced combat Soldiers ($n = 27$) participated in a combat training exercise of ~ 120 hr while wearing the VSIDS. They were then given a questionnaire to assess comfort, physical impact on the body, and acceptability of the VSIDS as well as questions on fit, impact on performance, and durability of the VSIDS. Comfort was impacted the most by the VSIDS when in the prone position, possibly affecting sleep, and prone position rifle shooting. Skin irritation or discomfort was reported in 85% of respondents. Sixty-two percent thought the VSIDS was not acceptable to wear for ≥ 8 hr. Yet, at the same time, 92% of Soldiers approved of the concept for health monitoring, and 89% said they would wear the VSIDS as is if it could help save their life. The VSIDS needs to be modified to be more comfortable before it can be fielded for medical monitoring of Soldiers in the field.

INTRODUCTION

Medics overseeing the health of Soldiers during vigorous training or when deployed to the battlefield need rapid access to basic physiological information about individuals they may have to treat. Ambulatory monitoring may provide key information needed to make better decisions regarding the identity, location, and triage priority of casualties (Hoyt and Friedl, 2004). For instance, wearable monitors providing geo-location and vital signs such as heart rate and respiration could be used to monitor Soldiers' health and well-being. A medic is often located some distance away from a fallen Soldier. Providing the medic with a Soldier's physiological information and location via a radio network, will likely improve the medical care administered to that Soldier because he/she will be recognized as injured or sick sooner, and the nature of his/her problem will be known to a greater degree. The impact of comfort on wearable medical monitoring technologies has been recognized as an important aspect to its design (Healy, 2004; Meinander and Honkala, 2004). If the monitoring system is uncomfortable, the Soldier is less likely to wear it. Additionally, if wearing a system compromises the Soldier's ability to do his/her job, the benefit of the system is greatly reduced. The

purpose of this study was to assess the human factors issues of wearing the VSIDS by Soldiers during its intended use, a combat scenario.

OVERALL METHOD

Participants

Twenty-seven male Soldiers (age: mean = 28.0 $SD = 5.1$ yrs; yrs of service: mean = 8.3 $SD = 4.8$ yrs) participated in an urban combat training experiment. All Soldiers had been deployed to Iraq on at least one combat mission within the previous year. Prior to the start of the study, participants were briefed on the purpose of the study, and the associated risks and benefits. They were informed of their right to withdraw at any time. Participants gave their written informed consent at this time. The study was approved by the Scientific and Human Use Review Committees at the U.S. Army Research Institute of Environmental Medicine. Soldiers were also briefed on the purpose of the Warfighter Physiological Status Monitoring (WPSM) system and were told they were going to be given an opportunity to provide feedback on the system after wearing it during their military training exercise.

Experimental Equipment

Volunteers wore a prototype physiological monitoring system called the WPSM system (Figure 1). The system consists of 1) a Vital Sign Detection System (VSDS) which measures heart rate, respiration rate, body motion and body position, 2) a fluid intake monitor (FIM), 3) a sleep watch that estimates sleep through actigraphy, 4) a skin temperature patch, and 5) a health hub that hosts the WPSM sensor network and algorithms such as determining life sign status or estimation of thermal injury to the Soldier.



* This study focused only on the VSIDS part of the WPSM system

Figure 1. Schematic of the Warfighter Physiological Status Monitoring (WPSM) system.

Procedures

Prior to the start of the exercise, body weight, height, and chest circumference measurements were obtained. Volunteers were fitted with the appropriate sized VSIDS based on the manufacturer's sizing chart. The VSIDS consists of a belt worn around the chest with a shoulder strap to hold it in place, and a hard plastic sensor electronics module (SEM). The SEM houses the heart rate and respiration rate sensors, batteries, and sensors for body motion and position. The SEM is attached to the chest belt by snaps.

All Soldiers completed a combat exercise that consisted of approximately 120 hours of training over 7 days including one 24-hour

sustained operation. On the final day of training after all training exercises were completed, participants were asked to fill out a questionnaire about the fit, comfort, performance, physical impact, durability, and acceptability of the VSIDS. The questionnaire used questions previously developed by Knight and Baber (2005) on comfort, and 18 other yes/no, Likert-scaled, or open-ended questions to obtain the information necessary to assess these human factors issues.

SURVEY METHOD AND RESULTS

Fit

To assess fit, Soldiers were asked on a 7-point scale about how loose or tight the device was on them (very tight = 1, neither tight nor loose = 4, to very loose = 7). In addition, they were asked about how much they liked the way the VSIDS fit (dislike very much = 1 to like very much = 7). Approximately 77% of Soldiers felt the VSIDS fit them properly. A rating of mean = 3.0, $SD = 1.0$ was obtained (3.0 = slightly tight) for how loose or tight the device was on them. A rating of mean = 3.2, $SD = 0.9$ was obtained (3.0 = dislike slightly and 4.0 = neither like nor dislike) regarding how they liked the fit. The reasons offered for poor fit were 1) that the buckles or another part of the system dug into the skin ($n = 3$; 12%); 2) the system loosened over time ($n = 3$, 12%); 3) the system did not fit as well as if sensors were woven into a shirt ($n = 1$, 4%); 4) the system became uncomfortable when sweaty ($n = 1$, 4%); and 5) it was too tight and restrictive but at the same time the SEM stuck out too far ($n = 1$, 4%).

Comfort

Using the 20-point scales developed by Knight and Barber (2005), the following comfort rating scale dimensions were measured: 1) emotion (does wearing the device make one worry about how they look), 2) attachment (can one feel the device on the body in a negative way), 3) harm (will the device cause physical harm to the body), 4) perceived change (does one feel physically different wearing the device), 5) movement (does the device

restrict or alter movement), and 6) anxiety (will the device impact one's safety by wearing it). Each of these comfort sub-factors were measured on a 20-point scale and the results of these comfort measures are shown in Table 1.

Table 1. Rating scores* from Knight and Baber (2005) rating scale on assessing comfort of wearable computers.

Comfort Scale	Mean (SD)	
Emotion	1.9	3.4
Attachment	10.1	6.7
Harm	4.5	5.6
Perceived Change	5.2	6.5
Movement	5.3	6.0
Anxiety	2.8	4.6

* Scores range from "0" = low (good) to "20" = High (bad).

Soldiers were also asked additional questions about comfort of the VSDS during sleep and load carriage exercises (i.e., when carrying a rucksack). Using a 7-point scale (very uncomfortable = 1 to very comfortable = 7), they reported ratings for these activities of mean = 3.0, *SD* = 1.7 for sleep and mean = 3.4, *SD* = 1.1 for load carriage exercises (3.0 = slightly uncomfortable and 4.0 = neither comfortable nor comfortable). Soldiers were also asked in an open-ended format if there was a particular activity where wearing the VSDS was uncomfortable. Thirty percent said while doing activities in the prone position like shooting or low crawling. In addition, 26% and 15% respectively, indicated that it was uncomfortable while sleeping/resting and after they became sweaty.

Impact on Military Performance

Soldiers were asked to rate the impact of the VSDS while wearing their standard Battle Dress Uniform (BDU), wearing BDUs plus body armor, and specifically during load carriage exercises. They were asked to give ratings on a 5-point scale (extreme negative impact = 1 to no impact = 5) for each of these conditions for the following activities; overall performance, ease of motion, ease of body

movement, rolling, bending, jumping, landing, running, and assuming a firing position. Only 13 Soldiers wore body armor at any time. Table 2 shows the mean negative impact of those activities with a "greater than slight impact." These results show Soldiers experienced a negative impact when trying to assume a firing position whether they were in BDUs only, were wearing body armor, or as part of load carriage-type exercises. In addition, it can be seen that a negative impact on performance was reported for all activities when wearing body armor. It should be noted that wearing body armor is uncomfortable to begin with.

Table 2. Ratings* on the negative impact of wearing the VSDS on military performance.

Condition and Activity	Mean (SD)	
BDUs Only (n=26)		
Rolling	3.7	1.4
Assuming a Firing Position	3.3	1.6
Wearing Body Armor (n=13)		
Overall Performance	3.4	1.7
Ease of Motion	3.5	1.7
Ease of Body Movement	3.5	1.7
Rolling	2.9	1.7
Bending	3.2	1.8
Jumping	3.4	1.8
Landing	3.1	1.6
Running	3.5	1.7
Assuming a Firing Position	2.9	1.7
During Load Carriage (n=26)		
Overall Performance	3.8	1.3
Landing	3.7	1.7
Bending	3.8	1.4
Assuming a Firing Position	3.3	1.7

*Ratings are 5 = No Negative Impact, 4 = Slight Negative Impact, 3 = Moderate Negative Impact, 2 = Very Negative Impact, 1 = Extreme Negative Impact

Physical Impact on the Body

When Soldiers were specifically asked if wearing the VSDS caused any skin irritation or discomfort, approximately 85% responded that it did. Soldiers were then asked the degree of impact (extreme negative impact = 1 to no impact = 5) on a 5-point scale. The average rating was mean = 3.7, $SD = 1.2$ (3.0 = moderate negative impact and 4.0 = slight negative impact). When Soldiers were asked what specific problem they experienced, 41% of those that said there was a negative impact indicated the VSDS caused itching of the skin, while another 36% said the device caused skin irritation, redness, sensitivity or abrasion. Other negative impacts reported by one or two individuals included; it caused acne, prickly heat, extreme sweating, and muscle cramps. When asked about the body location of the negative physical impact, 46% of those who experienced a negative impact reported it affected their chest, 41% their back, 27% their shoulder, and 14% under their arms. When asked which of the various components of the VSDS such as the electrodes, stitching, shoulder strap etc. that caused the problem; the central belt area and the adjustment buckle were rated as the most problematic with average ratings between moderate negative impact and slight negative impact.

Durability

Soldiers were asked to report and make note if the system broke during this test. Only 5 Soldiers reported that the device broke during the test. However, the research staff who outfitted and received the equipment each day from the Soldiers recorded when the devices were returned broken or not attached (SEM to the belt) in the proper way. Research staff identified that 26% of the SEM units failed at least once during this study. The two common failures were that the VSDS could not be turned on electronically or data was lost. Causes were that the bungs (a small rubber-plastic device that covers some electronic pins) fell out during the exercise and/or the SEM units became partially detached from the belt, mostly at the sides because the snaps came undone.

There were also 4 belt failures. Three had at least one metal snap torn out of the five that are normally present. The other belt had torn foam (used for padding and comfort) near the center of the belt where the SEM attaches to the belt.

Acceptability

Soldiers were asked if the VSDS would be acceptable to wear for 8 hours or more, 62% said it was not. When asked why it would not be acceptable in an open-ended format question; 41% cited that it was uncomfortable, dug in to the skin, caused rashes, abraded the skin, or was itchy. Other reasons cited, were “that you cannot sleep with it on”, “it stinks” (odiferous), “it is not compatible with wearing body armor”, “it comes loose”, and “it affects performance of military tasks during combat” ($n = 1$, 4% for each of these reasons).

When Soldiers were asked about how useful or not useful they thought the VSDS would be in monitoring their health, 92% reported that it would be slightly to very useful, with 54% stating that it would be very useful. When asked if they would wear the complete WPSM system including the VSDS as currently configured if it helped prevent and injury while in training or combat, 82% of Soldiers said they would. When asked if they would wear the complete WPSM system as currently configured if it could help save their life or provide them with better medical care, 89% of Soldiers said they would. For those who answered no, to why they wouldn't wear it, one Soldier said “the system needs to be wear and forget, it isn't and it doesn't work well enough right now” while the other Soldier said that “the equipment does not give enough critical information for the weight, upkeep, and expense it is likely to add.”

DISCUSSION

Based on the feedback from this user group it was demonstrated that these combat-experienced Soldiers felt the WPSM system with the VSDS was a valuable device for monitoring their health state. However, there are a number of human factors issues that need to be resolved before the device can

be fielded for its intended use. As such, the results of this study have been forwarded to the manufacturer of the system, and improvements to the system continue to be made. This study demonstrates the need for a comprehensive test and evaluation of new products for the military and other users to ensure new products “do no harm” as well as provide the intended positive benefits.

The discomfort when wearing the VSDS while lying in the prone position was one of the most salient pieces of information to be learned from this study. This information is important because it directly can affect mission performance. Accuracy of rifle shooting was reported to be compromised because the discomfort of lying on the hard plastic electronics casing (i.e., the SEM) positioned in the middle of the chest affects breathing and the assumption of a safe and stable (low to the ground) shooting position. In addition, the discomfort associated when sleeping is critical because often Soldiers are already sleep-deprived during combat operations. Disruptions of sleep during the few tactical periods when they are able to get sleep need to be avoided because sleep-deprivation is especially detrimental to cognitive decision-making capabilities (Hursh et al., 2004).

Future development of the system may include softer fabrics for the belt of the VSDS, a smaller plastic casing to hold the electronics for heart rate and other VSDS measures, a more flexible electronics casing, and/or repositioning of the electronics casing.

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REFERENCES

- Healy, J. (2004). Challenges of ambulatory physiological monitoring. *Studies in Health Technology and Informatics*, 108:95-102.
- Hoyt, R.W. and Friedl, K.E. (2004). Current status of field applications of physiological monitoring for the dismounted soldier. In: *Monitoring Metabolic Status: Predicting Decrements in Physiological and Cognitive Performance* (pp. 247-257). Washington, D.C.: National Academies Press.
- Hursh, S. R., Redmond, S.P., Johnson, M.L., Thorne, D.R., Belenky, G., Balkin, T.J. et al. (2004). Fatigue models for applied research in warfighting. *Aviation, Space, and Environmental Medicine*, 75(3): A44-A53.
- Knight, J.F. and Baber, C.A. (2005). Tool to assess the comfort of wearable computers. *Human Factors*, 47(1): 77-91.
- Meinander, H. and Honkala, M. (2004). Potential applications of smart clothing in health care and personal protection. *Studies in Health Technology and Informatics*, 108:275-285.